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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/075,593 | 02/15/2002 | Ellen M. Heath | GISM-P01-011 | 9392 |
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| Ropes & Gray Suite 800 East 1301 K Street, NW Washington, DC 20005 | | | | |
| | | | EXAMINER STRZELECKA, TERESA E | |
| | | | ART UNIT 1637 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/075,593

Applicant(s)

HEATH ET AL.

Examiner

Teresa E. Strzelecka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-17,19-28,30-38,40-49,51-59 and 61-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-17,19-28,30-38,40-49,51-59 and 61-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 9, 2007 has been entered.
2. Claims 1-7, 9-17, 19-28, 30-38, 40-49, 51-59 and 61-65 were previously pending. Applicants did not amend any claims. Claims 1-7, 9-17, 19-28, 30-38, 40-49, 51-59 and 61-65 will be examined.
3. Applicants' arguments overcame the previously pending rejections. This office action contains new grounds for rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 11, 12, 16, 32, 33, 37, 53, 54 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 11, 32 and 53 are indefinite over the recitation of "the concentration of the salt is greater than about 1 M". The phrase "greater than" typically indicates a minimum point. The phrase "greater than" however, is contraverted by the term "about" which implies that values above and below 1 M are permitted. Further, the extent of variance permitted by about is unclear

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in this context, since Applicants did not define the range of values which correspond to the term "about". Therefore, it is unclear what are the metes and bounds of these claims.

B) Claims 12, 33 and 54 are indefinite over the recitation of "the concentration of the salt is greater than about 2 M". The phrase "greater than" typically indicates a minimum point. The phrase "greater than" however, is contraverted by the term "about" which implies that values above and below 2 M are permitted. Further, the extent of variance permitted by about is unclear in this context, since Applicants did not define the range of values which correspond to the term "about". Therefore, it is unclear what are the metes and bounds of these claims.

C) Claims 16, 37 and 58 are indefinite over the recitation of "the concentration of the anionic detergent is greater than about 0.1% w/v". The phrase "greater than" typically indicates a minimum point. The phrase "greater than" however, is contraverted by the term "about" which implies that values above and below 0.1% are permitted. Further, the extent of variance permitted by about is unclear in this context, since Applicants did not define the range of values which correspond to the term "about". Therefore, it is unclear what are the metes and bounds of these claims.

Claim Interpretation

6. Applicants defined the term "hypertonic solution" on page 10, second paragraph:

" The first reagent, referred to herein as a "hypertonic, high-salt reagent," is a hypertonic reagent that includes a high concentrations of salts such as sodium, ammonium, or potassium salts dissolved in water. A hypertonic solution is a solution having a higher osmotic pressure than that found within a biological entity such as a cell or tissue."

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-7, 9-16, 19-28, 30-37, 40-49, 51-58 and 61-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fairman (US 2002/0068280 A1; cited in a previous office action).

A) Claims 1, 2, 24 and 45 will be considered together in claim 45, since it is a species of claims 1, 2 and 24.

Regarding claims 1, 2, 24 and 45, Fairman teaches a method of isolating DNA from a biological sample comprising red and white blood cells, the method comprising the following sequential steps:

(a) contacting the biological sample with a red blood lysis reagent to lyse the red blood cells (Fig. 1, step 120; page 1, [0010]; page 2, [0022]; page 3, [0027], [0028]);

(b) separating the white blood cells from the lysed red blood cells (Fig. 1, step 130; page 2, [0022]; page 3, [0029]);

(c) contacting the white blood cells with a hypertonic, high-salt reagent to suspend the white blood cells in a solution of said hypertonic, high-salt reagent (Fig. 1, step 130; page 2, [0022]; page 3, [0026], [0030]; since the second solution contains salt concentration of about 200-300 mM, it is a hypertonic solution);

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(d) subsequently contacting the white blood cells of step (c) with a lysis reagent so as to lyse the biological material containing DNA to form a lysate containing DNA and non-DNA cellular material (Fig. 1, step 140; page 2, [0022]; page 3, [0031]) and

(e) separating the DNA from non-DNA cellular material of the lysate to yield isolated DNA (Fig. 1, steps 150, 160; page 2, [0022]; page 4, [0034]-[0040]; page 5, [0041]).

Regarding claims 3, 6, 25, 27, 46 and 48, Fairman teaches whole blood (page 2, [0022]).

Regarding claim 4, Fairman teaches whole blood (page 2, [0022]), therefore they inherently teach samples containing viruses.

Regarding claims 5, 26 and 47, Fairman teaches bone marrow (page 3, [0024]).

Regarding claims 7, 28 and 49, Fairman teaches separating the DNA from proteins (page 4, [0035]).

Regarding claims 13-16, 34-37 and 55-58, Fairman teaches using 0.1% w/v SDS in the lysis solution (page 2, [0022]).

Regarding claims 9-11, 30-33 and 51-54, Fairman teaches ammonium salt solutions with concentration of about 0.2-0.3 M (page 3, [0026]) and using 5 M solution of ammonium acetate to precipitate proteins (page 4, [0035]).

Regarding claims 19, 20, 40, 41, 61 and 62, Fairman teaches removal of the protein precipitate by centrifugation (page 4, [0037]).

Regarding claims 21, 22, 42, 43, 63 and 64, Fairman teaches precipitation of DNA with alcohol and centrifugation (page 5, [0041]), i.e. they teach precipitation and washing of the DNA.

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Regarding claims 23, 44 and 65, Fairman teaches using the DNA in a PCR reaction, i.e. rehydrating the DNA (page 5, [0040]).

B) Fairman does not teach adding the high-salt solution which precipitates the DNA before lysing the cells.

However, it would have been *prima facie* obvious to one of ordinary skill in the art to have reversed the steps of adding a high-salt solution before cell lysis. As stated in several Court decisions, changing the order of steps is *prima facie* obvious (see MPEP 2144.04.IV.C):

Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render *prima facie* obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.).

9. Claims 17, 38 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fairman (US 2002/0068280 A1; cited in a previous office action) and Hanak et al. (U.S. Patent No. 6,780,632 B1).

A) The teachings of Fairman et al. are presented above. The reference does not teach using RNase in the purification protocol.

B) Hanak et al. teach preparing RNA-free DNA using RNase (Abstract; col. 2, lines 30-35; col. 35, lines 46-67; col. 36; col. 37; col. 38, lines 1-44).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used RNase of Hanak et al. in the DNA preparation method of Fairman.

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The motivation to do so, provided by Hanak et al., is that RNA is a major contaminant of preparations of genomic and plasmid DNA from cell lysates (col. 1, lines 36-50).

10. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

Teresa Strzelecka
7/20/07